10049916 .072102
JC10 Rec'd PCT/PTO 19 FEB 2002

FORM PTO-1390 (REV. 1-98) U S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER
S0441/270427

U S. APPLICATION NO (If known, see 37 CFR 1 5)
unknown 10/049916

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/23267	24 August 2000 (24.08.00)	24 August 1999 (24.08.99)

TITLE OF INVENTION
COMBINATION OF PROCESSES FOR MAKING WROUGHT COMPONENTS

APPLICANT(S) FOR DO/EO/US
LONG, Marc and HUNTER, Gordon

Applicants herewith submit to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 37 (b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as published (35 U.S.C. 371(c)(2))
   - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   - b. ☐ has been transmitted by the International Bureau.
   - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the published International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   - b. ☐ have been transmitted by the International Bureau.
   - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unexecuted)
10. ☐ A translation of the annexes of the International Preliminary Examination Report under PCT Article 36
11. ☐ An Information Disclosure Statement under 37 CFR 1.197 and 1.98
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
    - a. Certification Under 37 CFR 1.10

I hereby certify that this document is being mailed to Box PCT, Commissioner for Patents, Washington, D.C. 20231, via "Express Mail Post Office to Addressee" on this 19TH day of February, 2002, Express Mail Label No. EL209599746US

Angela M. Rossi Angela M. Rossi

1305071

10049916 .021902

JC10 Rec'd PCT/PTO 19 FEB 2002

U.S. APPLICATION NO (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
10/049916	PCT/US00/23267	S0441/270427

17. ☒ The following fees are submitted BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):		CALCULATIONS	PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO	$1,040.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$890.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2) paid to USPTO	$740.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)	$710.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)	$100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT	=	$890.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		$130.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total claims	69	49	X $18.00	$882.00	
Independent claims	08	05	X $84.00	$420.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+$280.00	$.00	
TOTAL OF ABOVE CALCULATIONS			=	$2,322.00	
Reduction of ½ for filing by small entity, if applicable.			--	$.00	
SUBTOTAL			=	$2,322.00	
Processing fee of $130.00 for furnishing the English translation later than ☐20 ☒30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$.00	
TOTAL NATIONAL FEE			=	$2,322.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40 per property				$.00	
TOTAL FEES ENCLOSED			=	$2,322.00	
				Amount to be refunded:	$
				charged:	$

a. ☒ Check in the amount of $2,322.00 is enclosed.

b. ☐ Please charge my Deposit Account No. 11-0855 in the amount of $_______ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-0855.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.

Customer No. 23370

SEND ALL CORRESPONDENCE TO:

John S. Pratt, Esq.
KILPATRICK STOCKTON LLP
1100 Peachtree Street, Suite 2800
Atlanta, Georgia 30309-4530

James L. Ewing

SIGNATURE

Name: James L. Ewing, IV

Registration No. 30,630

1305071

10/049916
JC10 Rec'd PCT/PTO 19 FEB 2002

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Applicants:	LONG, Marc and HUNTER, Gordon
International Application No.:	PCT/US00/23267
U.S. Serial No.:	
International Filing Date:	24 August 2000 (24.08.00)
U.S. Filing Date:	19 February 2002 (19.02.02)
For:	COMBINATIONS OF PROCESSES FOR MAKING WROUGHT COMPONENTS

Box PCT
Commissioner for Patents
Washington, D.C. 20231

Attorney Docket No. s0441/270427
Date: 19 February 2002

PRELIMINARY AMENDMENT

Sir:

Kindly amend the above-identified patent application prior to examination:

In the Specification

On page 1, immediately following the title "Combination of Processes for Making Wrought Components" kindly insert the following paragraph:

--This application claims priority to U.S. Provisional Application No. 60/150,429 filed on August 24, 1999 and International Application No. PCT/US00/23267 filed on August 24, 2000 and published in English as International Publication Number WO 01/14602 A2 on March 1, 2001, the entire contents of each are hereby incorporated by reference.--

Express Mail Label No. EL209599746US
U.S. National Phase Entry of PCT/US00/23267
Filed: 19 February 2002
PRELIMINARY AMENDMENT

Respectfully submitted,

James L. Ewing, IV
Reg. No. 30,630

KILPATRICK STOCKTON LLP
1100 Peachtree Street, Suite 2800
Atlanta, Georgia 30309
(404) 815-6500

101 Rec'd PCT/PTO 19 FEB 2002

10/049916

Combination of Processes for Making Wrought Components

The present invention relates to metal objects which may be formed using casting, incremental forming, or consolidation processes followed by wrought processes. Such objects exhibit favorable properties, including ductility and strength, with reduced cost and lead-time.

Background

Processes for forming metal objects, including casting and forging processes, are generally well known. Various forms of casting processes and forging processes have been in use since the Bronze Age. In more recent times, certain casting processes have been combined with certain forging processes to improve properties of materials and objects. Thus, U.S. Patent No. 4,775,426 issued October 4, 1988 to Murley, et al., incorporated herein by this reference, discloses manufacture of a surgical implant by investment casting stainless steel and then cold-forging to final shape, in order to reduce porosity of the material and increase its strength compared to a machined product from a wrought material. U.S. Patent No. 5,729,883 issued March 24, 1998 to Yoshioka et al. and incorporated herein by this reference discloses manufacture of an automobile wheel by casting an aluminum alloy and then forging it, including applying a processing degree of not less than 15% and stress of not less than 50 MPa to parts of the wheel to improve strength and impart a smooth and highly glossy surface. International Publication Number WO 98/42460 dated October 1, 1998 owned by Komtek, Inc. and incorporated herein by this reference discloses investment casting metal alloys using a single-use ceramic mold to form a preform blank and then subjecting the blank to extrusion, closed die forging or both to produce desired mechanical properties and microstructure. None of these disclosures, however, focus on a casting process that utilizes a permanent mold, preferably of metal, for rapid heat removal to achieve ductility and a refined grain structure in the cast material

sufficient to allow the wrought process step to produce orthopaedic or other surgical components with strength and ductility comparable to conventional wrought orthopaedic or surgical components. Nor do these disclosures focus on pre-wrought processes that achieve the necessary ductility and refined grain structure for wrought processing through rapid heat removal through the component or a quenching atmosphere. Nor do these disclosures focus on pre-wrought processes that achieve the necessary ductility and refined grain structure through consolidation of powder or semi-solid material under conditions which restrict coarsening of the grain structure.

Summary

The present invention combines pre-wrought processes with conventional wrought processes to produce wrought orthopaedic components at reduced cost and lead-time, but comparable to conventional forgings in ductility and strength. Potentially, any orthopaedic alloy, such as Co-28Cr-6Mo, stainless steel, Ti-alloys or Zr-alloys, may be manufactured using the combined processes according to this invention. These combined processes may also apply to several orthopaedic components, such as hip stems, knee femorals, tibial trays, or skeletal fixation plates. For example, this invention could easily be applied to forged hip stems and tibial trays made of either Co-28Cr-6Mo or Ti-6Al-4V.

In this invention, the wrought barstock used conventionally for forging feedstock is replaced with a bar or preform cast in metal molds and exhibiting the required ductile strength and refined grain structure to be forgeable. Other methods for producing a bar or preform with sufficient forgeability may be used such as metal powder consolidation forming, metal injection molding, solid free form fabrication, metal rapid prototyping, laser and electron beam forming, spray forming, and semi-solid forming processes, so long as the process produces the fine grain structure and ductility, and if desired, low-notch brittleness and other properties according to the present invention as discussed herein. Thus, in addition to forming the pre-wrought material using a metal mold, there are at least two other categories of pre-

wrought processes according to the present invention: (1) processes that achieve the necessary ductility and refined grain structure for wrought processing through rapid heat removal through the component or a quenching atmosphere; and (2) pre-wrought processes that achieve the necessary ductility and refined grain structure through consolidation of powder or semi-solid material under conditions which restrict coarsening of the grain structure.

This material, bar or preform may then be forged using one or more forging or wrought processes to produce grain size refinement and increase in material integrity. Appropriate forging or wrought methods that give the final shape and properties to the material, bar or preform include: presses (screw, mechanical, hydraulic), hammering, rolling, extruding or upsetting, cold forging, any thermal / mechanical forming process, or any other suitable process for producing wrought metal objects. The term "forging" as used in this document means any or all of such processes.

According to one version of the invention, which can be considered optional, material for the wrought process is produced using metal mold casting or another forming process which produces requisite ductility and grain size, and then preshaped. One option is to produce an oversized bar in the shape of wrought barstock which would be subsequently swaged, upset, extruded, or bent to distribute the material closer to the shape of the final product. A second option is to utilize an oversized preform shape resembling the final product. The preshaped bar or preform is subsequently forged to produce an orthopaedic product that meets the minimum requirements specified in appropriate industry standards for conventionally forged products.

Materials suitable for processes according to the present invention include CoCr alloys. Alloys similar to CoCr alloys can also be appropriate, for example Ni-alloys. In these systems, the maximum forging temperature is limited by dissolution or precipitation of second phases. In addition, the material to be forged must have a refined grain structure in order to prevent cracking or non-uniform flow during the forging operation. Other alloy systems which would require a refined grain size to

be made forgeable may also be processed according to the present invention. In some alloy systems, such as Ti-alloys or Zr-alloys, high forging temperatures are required to break down a coarse cast grain structure; an intermediate step is often required to refine the original cast structure. Starting with a refined grain structure in accordance with the present invention may eliminate this additional step and reduce cost.

The present invention can also be used to produce original alloy compositions that are not commercially available in barstock form. Pre-wrought processes according to the invention allow for the production of new alloys not currently available, such as new or custom alloy compositions. These alloys can then be wrought to produce high quality products which could not be produced by the conventional barstock/forging method cost-effectively. A refined grain size is again required to make these new alloys forgeable. For example, new titanium, zirconium or stainless steel alloy compositions may fall into this category.

The combined processes according to the present invention may be used to produce a variety of orthopaedic components, including but not limited to: total hip systems: stems, femoral heads, unipolar heads, distal sleeves, trial necks, bipolar shells, stem endoprosthesis; acetabular systems: shells, rings; total knee systems: femoral components, femoral lugs, tibial components, conversion modules, wedges, stems; total shoulder systems: stem humeral components, glenoid metal-backed components, skeletal fixation systems: hip screw nails, hip screw plates, screws, pins, rings, posts, cubes; instrumentation: possibly all metallic instruments including broaches, reamers, collets, guides, handles, trials, osteotomes, impactors, and cutting blocks.

Advantages of processes according to the invention over conventional use of wrought barstock as forging feedstock include a reduction in product cost through reduction in material cost (less material used and less scrap), reduction of the number of operations involved in making the final product, and reduction in delivery and manufacturing lead time. Advantages of the permanent mold casting processes of the invention over using disposable ceramic shells in investment casting for bar or

preform production include reduction in processing cost through reduction in the number of operations involved in the casting process, reduction in manufacturing lead time, enhanced casting process repeatability, improved dimensional accuracy and stability of the castings, and reduction of impurities in the casting.

Brief Description of the Drawings

Figure 1 is a schematic process flow diagram for a conventional casting process.

Figure 2 is a schematic process flow diagram for a first set of pre-wrought processes according to the present invention.

Figure 3 is a schematic process flow diagram for a second set of pre-wrought processes according to the present invention.

Figure 4 is an optical micrograph of metal mold cast Co-28Cr-6Mo from Example 1, as discussed below.

Figures 5-1, 5-2, 5-3, 5-4, 5-6 and 5-7 are optical micrographs of compression tested metal mold cast Co-28Cr-6Mo with respective specimen numbers from Example 1, as discussed below.

Figures 6a and 6b, left and right respectively, are optical micrographs of conventional wrought Co-28Cr-6Mo.

Figures 7a and 7b, left and right respectively, are optical micrographs of metal mold cast Co-28Cr-6Mo from Example 2, as discussed below.

Figures 8a and 8b, left and right respectively, are optical micrographs of conventional investment cast Co-28Cr-6Mo.

Figure 9 is an optical micrograph of MIM Co-28Cr-6Mo.

Detailed Description

According to the present invention, wrought barstock used conventionally for forging feedstock is replaced with a metal mold cast bar, perform or other material exhibiting the required ductile strength and refined grain structure to be forgeable. Other methods for producing a bar or preform with a sufficient forgeability may be used such as metal powder consolidation forming, metal injection molding, solid free form fabrication, metal rapid prototyping, laser and electron beam forming, spray forming, and semi-solid forming processes, so long as the process provides sufficient heat transfer to impart a sufficiently rapid cooling rate in order to produce the fine grain structure and ductility, and, if desired, low-notch brittleness and other properties according to the present invention as discussed herein. This bar or preform may then be forged using a wrought process to produce grain size refinement and increase in material integrity. Thus, in addition to forming the pre-wrought material using a metal mold, there are at least two other categories of pre-wrought processes according to the present invention: (1) processes that achieve the necessary ductility and refined grain structure for wrought processing through rapid heat removal through the component or a quenching atmosphere; and (2) processes that achieve the necessary ductility and refined grain structure through consolidation of powder or semi-solid material under conditions which restrict coarsening of the grain structure.

Figure 1 show steps in a conventional casting process. As shown in Figure 2, any of the pre-wrought processes of the present invention mentioned in the paragraph above may be succeeded by a preshaping step before forging (and if necessary or desired, finishing). As shown in Figure 3, forging may occur without preshaping.

Appropriate forging methods which give the final shape and properties to the bar/preform include: presses (screw, mechanical, hydraulic), hammering, rolling, extruding or upsetting, cold forging, any thermal / mechanical forming process, or any other suitable process for producing wrought metal objects.

Objects of the pre-wrought process include to produce the bar or preform having at least sufficient ductility and refined grain size for the subsequent wrought process. Metal mold casting is the first category of such pre-wrought processes according to the present invention. Metal mold casting processes suitable for the present invention are disclosed in G. N. Colvin, "Permanent mold casting of titanium aerospace and automotive hardware", Titanium '95: Science and Technology, P. A. Blemkishop, W. J. Evans, and H. M. Flower, eds., The Institute of Materials, London, 691-701 (1995); G. N. Colvin, S. A. Salter, and A. L. Matthews (Howmet Corporation), "Permanent mold or die casting of titanium-aluminum alloys ", US Patent 5,505,246, April 9, 1996; and D. Larsen, "Vacuum diecasting yields quality parts", *Foundry Management & Technology*, February 1998, which are all incorporated herein by this reference.

Examples of the second category of pre-wrought processes according to the present invention, in which the necessary ductility and refined grain structure are obtained through rapid heat removal through the material, bar or preform already formed or accreted, or through a quenching medium or atmosphere, include laser and electron beam forming and spray forming, where the material accretes incrementally while heat flows into the material already formed and/or the medium or atmosphere, or both, during or after application of the material.

The third category of pre-wrought processes according to the present invention, includes processes that achieve the necessary ductility and refined grain structure through consolidation of powder or semi-solid material under conditions which restrict coarsening of the grain structure. An example of such a process is Metal Injection Molding (MIM) also known as Powder Metal Molding (PMM) and Powder Injection Molding (PIM). The MIM process involves combining metal powder with a polymer binder and injection molding the part. Once the part has been molded, the binder is removed, and the part is then sintered to increase the density of the part. These debinding and sintering operations must be conducted at temperatures and other conditions that prevent excessive grain coarsening of the metal. Suitable forms of MIM in accordance with the present invention are disclosed in the following

reference which is incorporated herein by this reference: R.M. German, Powder Metallurgy Science 2nd ed., Metal Powder Industries Federation, Princeton, NJ (1994).

The following examples are presented for the purpose of further illustrating and disclosing the invention and are not to be construed as a limitation thereof.

Example 1.

To demonstrate one example of this invention, fine grain specimens were produced for high temperature compression testing that simulates wrought processing. Metal mold casting was used to produce Co-28Cr-6Mo bars, about 1.5 cm (0.6 in) in diameter and 46 cm (18 in) in length. Specimens were machined from these bars to a diameter of 1.3 cm (0.5 in) and cut to length with a height to diameter aspect ratio of 1.2. Concentric grooves were machined on the top and bottom of the specimens and boron nitride spray was used at the specimen/die interface to minimize frictional effects. A small hole was drilled into the center of the specimen to place a thermocouple to monitor the temperature during testing. These specimens were tested on a high temperature, controlled atmosphere (argon) compression system. A matrix of process parameters included two temperatures (1125 and 1175°C), two strain rates (1 and 10 sec^{-1}), and three strains (0.10, 0.25, and 0.50) that were selected to be representative of practical forging parameters for CoCr alloys [See “Forging of heat-resist alloys, Forming and Forging, Volume 14, Metals Handbook Ninth Edition, ASM International, Ohio 231-36 (1998) which is incorporated herein by this reference.]. When the selected strain was produced, the specimens were gas-quenched using a high rate argon flow. The engineering stress/strain data were corrected for frictional effect and adiabatic heating. [See M. Long and H. J. Rack: “Thermo-mechanical stability of forged Ti-26Al-10Nb-3V-1Mo (at.%)”, *Materials Science & Engineering,* A194, 99-111 (1995) incorporated herein by this reference.]

None of the specimens exhibited cracking or indications of unstable deformation such as banding during or after compression testing, indicating good forgeability.

Six compressed specimens were selected and sectioned longitudinally, that is parallel to the compression axis, and prepared for metallography using standard techniques. Grain size was measured from both the center and the edges of each specimen using the circular intercept method in accordance with ASTM E112, which is incorporated herein by this reference. ASTM grain size numbers were generated and converted to diameter values. The pre-wrought metal mold cast microstructure was also prepared for comparison to the wrought microstructures.

The original metal mold cast microstructure is shown in Figure 4. All of the compression tests produced a reduction in grain size, as shown in Figure 5 (note the increase in magnification relative to Figure 4), although grain size refinement was not uniform across some specimens (specimen #2 for example). This indicated that recrystallization did not occur fully throughout the specimen. However, the parent grains from the original cast microstructure appeared always to be reduced. It appeared that higher temperature, faster strain rate, and large strain produced more uniform refined microstructure.

A summary of the grain size measurements is given in Table 1. The original grain size of the metal mold cast material was 293 μm. After deformation, average grain size values ranged from 10.8 to 17.1 μm. This represented approximately 95% reduction in grain size. For comparison, the grain size of a typical conventional wrought component (produced in accordance with ASTM F-799-96, which is incorporated by this reference) is 8.0 μm, as illustrated in Figure 6. Based on grain size measurements, the cast-forge material approaches grain sizes comparable to conventional wrought microstructures. It can then be expected that material processed in accordance with the present invention can have wrought-like properties acceptable for forged products.

Table 1. Summary of grain size measurements.

Condition [temperature, strain rate, strain]	Average Grain Size ± Standard Deviation [μm]	Specimen #
Conventional wrought material (typical)	8.0 ±2.5	
Metal mold cast bar	293.2 ±32.1	
1175°C, 10/sec, 0.50	14.6 ±2.7	1
1125°C, 1/sec, 0.25	17.1 ±1.5	2
1125°C, 10/sec, 0.50	10.8 ±3.0	3
1125°C, 1/sec, 0.50	13.8 ±2.9	4
1175°C, 10/sec, 0.25	12.6 ±2.2	6
1175°C, 1/sec, 0.50	15.4 ±2.4	7

Example 2.

It should be noted that greater reduction in grain size than demonstrated in Example 1 may be desired to achieve higher strength values after wrought processing. This may be achieved by reducing the grain size of the original pre-wrought material or by optimizing the wrought process.

A critical aspect of this invention is that the fine grain structure of the bar or preform provides improved ductile strength and sufficient forgeability to the material. It is believed that an elongation greater than 18% and an average grain size finer than 300 μm, and more preferably below 150 μm, are required for a Co-28Cr-6Mo bar/preform, such as produced by metal mold casting, to be wrought processed to produce a product with favorable properties. Average grain size values for conventional investment castings range from about 300 to 1400 μm, typical examples being shown in Figure 8. Castings that exhibit this range of grain size are considered to be not forgeable by the forging industry. Furthermore, refined carbides may also improve forgeability; large blocky carbides are typically observed in conventional investment castings. Metal mold casting of Co-28Cr-6Mo, such as for example the gravity metal mold casting process, can produce an average grain size of about 100 to 150 μm, as shown in Figure 7. Other metal mold casting

processes with faster heat removal, such as for example vacuum die casting, have the potential to produce even finer grain size.

In order to illustrate the advantage of a refined cast microstructure, the tensile properties of metal mold cast Co-28Cr-6Mo were determined and compared to that of conventional investment cast Co-28Cr-6Mo (produced in accordance with ASTM F-75-98 which is incorporated by this reference) and conventional wrought Co-28Cr-6Mo. Testing was performed in accordance with ASTM E8 (which is incorporated herein by this reference). The results shown in Table 2 show greater strength and ductility for metal mold cast material as compared to conventional investment cast material. These improved properties are believed to be associated with a grain size and carbide size in the metal mold cast material finer than in conventional investment cast material. The elongation of metal mold cast material is also similar to the minimum wrought values, demonstrating that a more refined pre-wrought microstructure can facilitate achieving favorable wrought properties.

Table 2. Properties of cast Co-28Cr-6Mo.

	Tensile [MPa]	Yield [MPa]	Elongation [%]
Metal mold cast	1041	593	20
Conventional investment cast (typical)	729	501	15.4
Conventional investment cast minimum (ASTM F75-98)	655	450	8
Conventional wrought (typical)	1337 – 1544	896 - 1247	20 – 35
Conventional wrought minimum (ASTM F799-96)	1172	827	12

Thus, these results demonstrate that the metal mold casting technology according to the present invention can produce CoCr products with properties acceptable for subsequent wrought processing.

Example 3.

To demonstrate one example of a powder consolidation process that may be used to produce the pre-wrought bar or preform, fine grain Co-28Cr-6Mo specimens were produced by Metal Injection Molding (MIM). MIM specimens, 10 mm (0.4 in) diameter by 89 mm (3.5 in) long were produced and subsequently Hot Isostatic Pressed (HIP'ed) and Solution Treated (ST). Testing was performed in accordance with ASTM E8. Specimens were prepared for metallographic analysis using standard techniques. The grain size of the specimens was determined using the circular intercept method in accordance with ASTM E112. The results for the MIM material were compared with corresponding results for typical conventional investment cast Co-28Cr-6Mo in the HIP + ST condition.

Table 3 shows the results for both materials. The MIM CoCr material exhibited 47% greater tensile strength, 6% greater yield strength, 145% greater ductility, and 4 to 20 times smaller grains compared to conventional investment cast CoCr. Figure 9 shows that both the grain size for the MIM material is more refined than for the conventional investment cast material shown in Figure 8. The MIM material also has more finely dispersed carbides than conventional investment cast material which are effective in impeding grain growth during the HIP and ST processes. The improved mechanical properties for MIM CoCr are attributed to its refined grain structure and fine carbide size.

Table 3. Properties of MIM Co-28Cr-6Mo (mean ± standard deviation).

(HIP + ST condition)	Tensile [MPa]	Yield [MPa]	Elongation [%]	Grain Size [μm]
MIM	1073 ± 23	532 ± 40	37.7 ± 3.3	69 ± 10
Conventional investment cast (typical)	729 ± 58	501 ± 13	15.4 ± 2.6	276 - 1414
Conventional investment cast minimum (ASTM F75-98)	655	450	8	--
Conventional wrought (typical)	1337 – 1544	896 - 1247	20 - 35	8.0 ± 2.5
Conventional wrought minimum (ASTM F799-96)	1172	827	12	--

Thus, these results demonstrate that the MIM, like metal mold casting, can produce pre-wrought barstock or preforms according to the present invention with properties acceptable for subsequent wrought processing.

The foregoing has been provided for disclosure of preferred embodiments of the present invention. Processes disclosed according to any of the three categories above may be varied, including by addition or deletion of steps, to produce a material with ductility and refined grain structure properties suitable for forging, without departing from the scope or spirit of the present invention.

What is claimed is:

1. A process for producing a component, comprising:

a. casting a blank using a metal mold which imparts sufficient conductive heat transfer from the blank to achieve rapid cooling of the blank in order to produce a blank which features a refined grain structure sufficient to prevent cracking or non-uniform flow during forging; and

b. subsequently forging the blank to produce said component.

2. A process according to claim 1 in which the blank is cast from a cobalt chrome alloy.

3. A process according to claim 2 in which the cobalt chrome alloy is a Co-28Cr-6Mo alloy.

4. A process according to claim 1 in which the blank is cast from a titanium alloy.

5. A process according to claim 1 in which the blank is cast from a zirconium alloy.

6. A process according to claim 1 in which the blank is cast from a stainless steel alloy.

7. A process according to claim 1 in which the casting process is a gravity metal mold process.

8. A process according to claim 1 in which the casting process is a vacuum die casting process.

9. A process according to claim 2 in which the blank after casting features a grain size smaller than 300 μm.

10. A process according to claim 2 in which the blank after casting features a grain size smaller than 150 μm.

11. A process according to claim 2 in which the blank after casting features an ultimate tensile strength of at least 665 MPa.

12. A process according to claim 3 in which the component after forging complies with ASTM F-799-96.

13. A process for producing an orthopaedic component, comprising:

a. casting a blank from a cobalt chrome alloy using a metal mold which imparts sufficient conductive heat transfer from the blank to achieve cooling of the blank in order to produce grain size smaller than 300 μm and ultimate tensile strength of at least 665 MPa; and

b. subsequently forging the blank to produce said component, the component complying with ASTM F-799-96.

14. A process according to claim13 in which the casting process is a gravity metal mold process.

15. A process according to claim 13 in which the casting process is a vacuum die casting process.

16. A process according to claim 13 in which the grain size of the blank is smaller than 150 μm.

17. A process for producing a component, comprising:

a. forming a blank by incrementally applying material to portions of the blank already formed, thus building the blank in a manner which imparts conductive heat transfer from the applied material to portions of the blank already built to achieve rapid cooling of the applied material in order to produce a blank which features a refined grain structure sufficient to prevent cracking or non-uniform flow during forging; and

b. subsequently forging the blank to produce said component.

18. A process according to claim 17 in which the material is also applied in a manner which imparts conductive heat transfer from the applied material to a gas surrounding the applied material to achieve cooling of the applied material.

19. A process according to claim 17 in which the blank is formed of a cobalt chrome alloy.

20. A process according to claim 19 in which the cobalt chrome alloy is a Co-28Cr-6Mo alloy.

21. A process according to claim 17 in which the blank is formed of a titanium alloy.

22. A process according to claim 17 in which the blank is formed of a zirconium alloy.

23. A process according to claim 17 in which the blank is formed of a stainless steel alloy.

24. A process according to claim 17 in which the forming process is a spray forming process.

25. A process according to claim 17 in which the forming process is an electron beam forming process.

26. A process according to claim 17 in which the forming process is a laser beam forming process.

27. A process according to claim 19 in which the blank after forming features a grain size smaller than 300 μm.

28. A process according to claim 19 in which the blank after forming features a grain size smaller than 150 μm.

29. A process according to claim 19 in which the blank after forming features an ultimate tensile strength of at least 665 MPa.

30. A process according to claim 20 in which the component after forging complies with ASTM F-799-96.

31. A process for producing an orthopaedic component, comprising:

a. forming a blank from a cobalt chrome alloy by incrementally applying material to portions of the blank already formed, thus building the blank in a manner which imparts conductive heat transfer from the applied material to portions of the blank already built and to a gas in the presence of the applied material to achieve rapid cooling of the applied material, the resulting grain size of the material in the blank smaller than 300 μm and the ultimate tensile strength of the material at least 665 MPa; and

b. subsequently forging the blank to produce said component, the component complying with ASTM F-799-96.

32. A process according to claim 31 in which the forming process is a spray forming process.

33. A process according to claim 31 in which the forming process is an electron beam forming process.

34. A process according to claim 31 in which the forming process is a laser beam forming processs.

35. A process according to claim 31 in which the grain size of the blank is smaller than 150 μm.

36. A process for producing a component, comprising:

a. forming a blank by consolidating a powderized material under at least temperature and pressure conditions sufficient to restrict coarsening of grain structure of the material in order to produce a blank which features a refined grain structure sufficient to prevent cracking or non-uniform flow during forging; and

b. subsequently forging the blank to produce said component.

37. A process according to claim 36 in which the blank is formed of a cobalt chrome alloy.

38. A process according to claim 37 in which the cobalt chrome alloy is a Co-28Cr-6Mo alloy.

39. A process according to claim 36 in which the blank is formed of a titanium alloy.

40. A process according to claim 36 in which the blank is formed of a zirconium alloy.

41. A process according to claim 36 in which the blank is formed of a stainless steel alloy.

42. A process according to claim 36 in which the forming process is a metal injection molding process.

43. A process according to claim 37 in which the blank after forming features a grain size smaller than 300 μm.

44. A process according to claim 37 in which the blank after forming features a grain size smaller than 150 μm.

45. A process according to claim 37 in which the blank after forming features an ultimate tensile strength of at least 665 MPa.

46. A process according to claim 38 in which the component after forging complies with ASTM F-799-96.

47. A process for producing an orthopaedic component, comprising:

a. forming a blank by metal injection molding a cobalt chrome alloy powder material to restrict coarsening of grain structure of the material, the resulting grain size of the material in the blank smaller than 300 μm and the ultimate tensile strength of the material in the blank at least 665 MPa; and

b. subsequently forging the blank to produce said component, the component complying with ASTM F-799-96.

48. A process according to claim 47 in which the grain size of the blank is smaller than 150 μm.

49. A process for producing a component, comprising:

a. forming a blank by consolidating a semi-solid material under at least temperature and pressure conditions sufficient to restrict coarsening of grain structure of the material in order to produce a blank which features a refined grain structure sufficient to prevent cracking or non-uniform flow during forging; and

b. subsequently forging the blank to produce said component.

50. A process according to claim 49 in which the blank is formed of a cobalt chrome alloy.

51. A process according to claim 50 in which the cobalt chrome alloy is a Co-28Cr-6Mo alloy.

52. A process according to claim 49 in which the blank is formed of a titanium alloy.

53. A process according to claim 49 in which the blank is formed of a zirconium alloy.

54. A process according to claim 49 in which the blank is formed of a stainless steel alloy.

55. A process according to claim 49 in which the forming process is a semi solid forming process.

56. A process according to claim 50 in which the blank after forming features a grain size smaller than 300 μm.

57. A process according to claim 50 in which the blank after forming features a grain size smaller than 150 μm.

58. A process according to claim 50 in which the blank after forming features an ultimate tensile strength of at least 665 MPa.

59. A process according to claim 51 in which the component after forging complies with ASTM F-799-96.

60. A process for producing an orthopaedic component, comprising:

a. forming a blank by semi-solid forming a cobalt chrome alloy material to restrict coarsening of grain structure of the material, the resulting grain size of the material in the blank smaller than 300 μm and the ultimate tensile strength of the material in the blank at least 665 MPa; and

b. subsequently forging the blank to produce said component, the component complying with ASTM F-799-96.

61. A process according to claim 60 in which the grain size of the blank is smaller than 150 μm.

62. A component formed according to the process recited in claim 1.

63. An orthopaedic component formed according to the process recited in claim 13.

64. A component formed according to the process recited in claim 17.

65. An orthopaedic component formed according to the process recited in claim 31.

66. A component formed according to the process recited in claim 36.

67. An orthopaedic component formed according to the process recited in claim 47.

68. A component formed according to the process recited in claim 49.

69. An orthopaedic component formed according to the process recited in claim 60.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 March 2001 (01.03.2001)

PCT

(10) International Publication Number
WO 01/14602 A2

(51) International Patent Classification[7]: C21D 7/00

(21) International Application Number: PCT/US00/23267

(22) International Filing Date: 24 August 2000 (24.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/150,429 24 August 1999 (24.08.1999) US

(71) Applicant *(for all designated States except US)*: SMITH & NEPHEW, INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: LONG, Mark [FR/US]; 911 Meda Street, Memphis, TN 38104 (US). HUNTER, Gordon [US/US]; 8394 Drury Lane, Germantown, TN 38139 (US).

(74) Agents: PRATT, John, S. et al.; Kilpatrick Stockton LLP, Suite 2800, 1100 Peachtree Street, Atlanta, GA 30309-4530 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/14602 A2

(54) Title: COMBINATION OF PROCESSES FOR MAKING WROUGHT COMPONENTS

(57) Abstract: The present invention combines pre-wrought processes with conventional forging processes to produce orthopaedic components at reduced cost and lead-time, but comparable to conventional forging in ductility and strength. In this invention, the wrought barstock used conventionally for forging feedstock is replaced with a preform, blank, bar or other pre-wrought material exhibiting the required ductile strength and refined grain structure to be forgeable. A critical aspect of this invention is that the fine grain structure of the pre-wrought material provides improved ductile strength and sufficient forgeability to the material. This bar or preform may then be forged to produce grain size refinement and increase in material integrity. Three categories of pre-wrought processes according to the invention include forming the material using metal molds; processes that achieve the necessary ductility and refined grain structure for wrought processing through rapid heat removal through the component or a quenching atmosphere or gas; and processes that achieve the necessary ductility and refined grain structure through consolidation of powder or semi-solid material under conditions which restrict coarsening of the grain structure.

Fig. 1

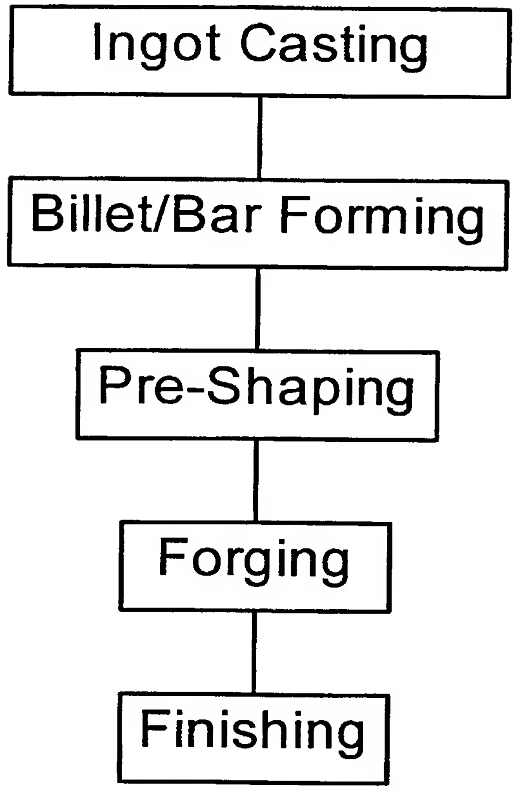

Ingot Casting
Billet/Bar Forming
Pre-Shaping
Forging
Finishing

Fig. 2

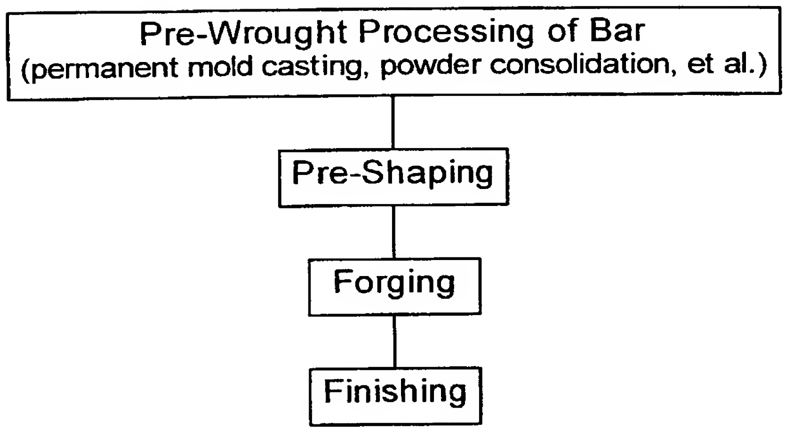

Pre-Wrought Processing of Bar
(permanent mold casting, powder consolidation, et al.)
Pre-Shaping
Forging
Finishing

Fig. 3

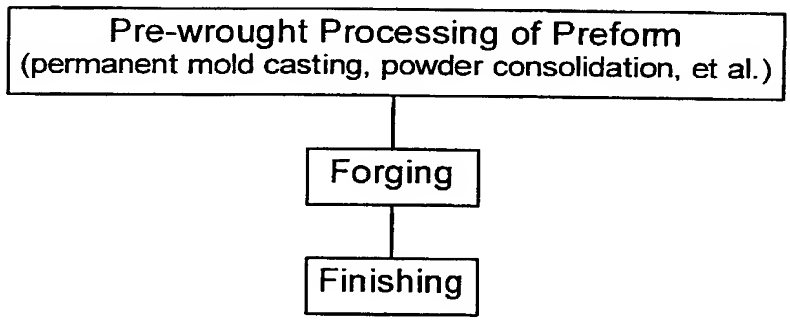
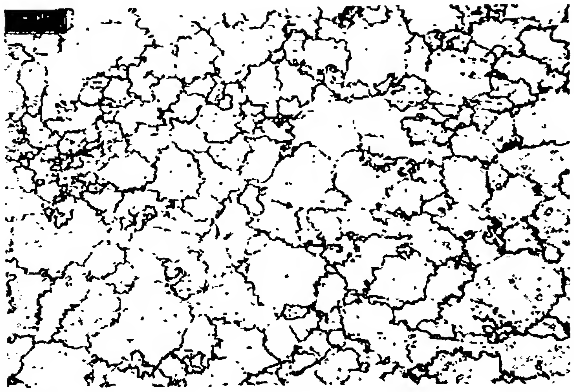
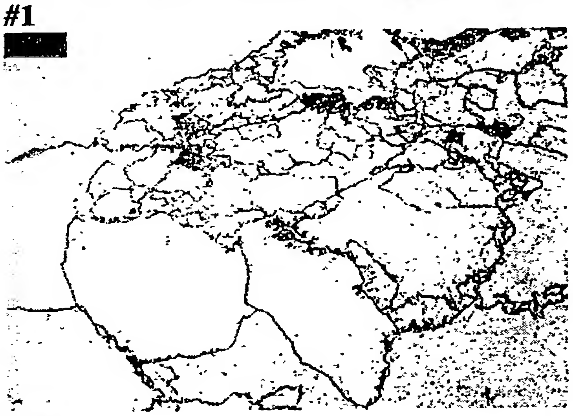

Pre-wrought Processing of Preform
(permanent mold casting, powder consolidation, et al.)
Forging
Finishing

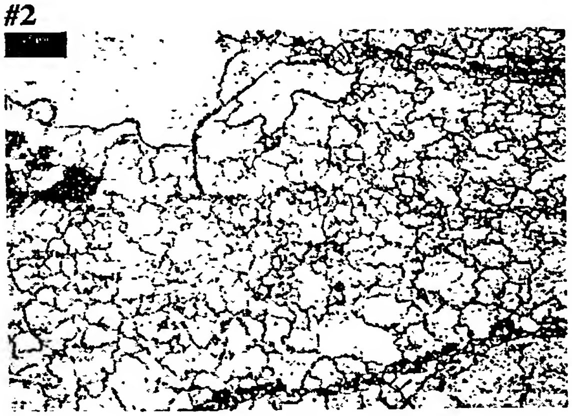
Figure 4.



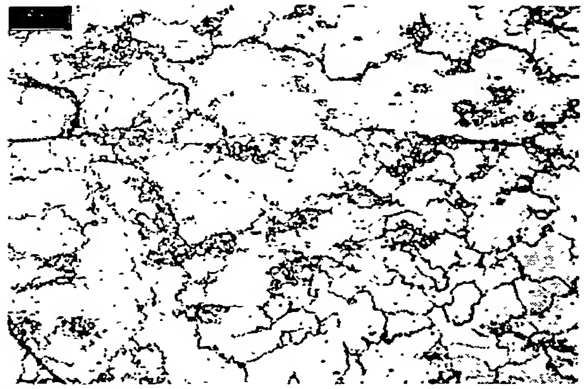
#1



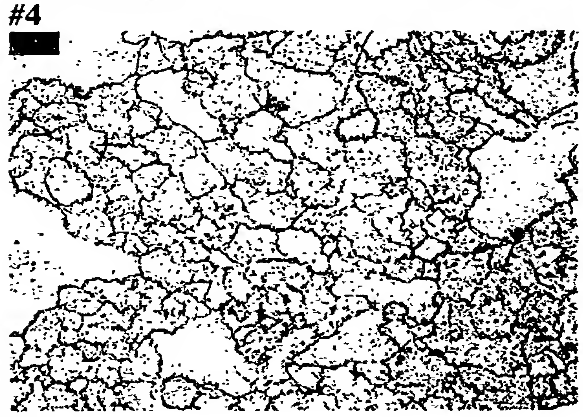
#2



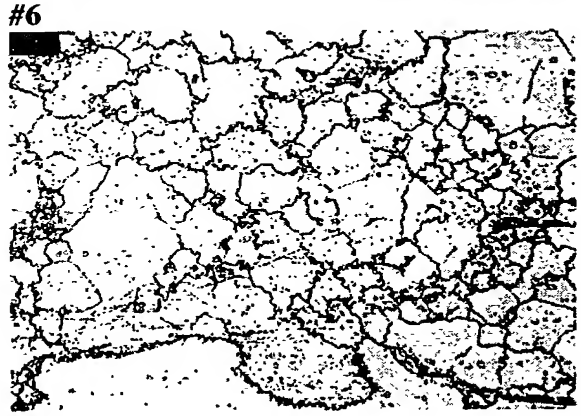
#3



#4



#6



#7

Figures 5-1, 5-2, 5-3, 5-4, 5-6 and 5-7.

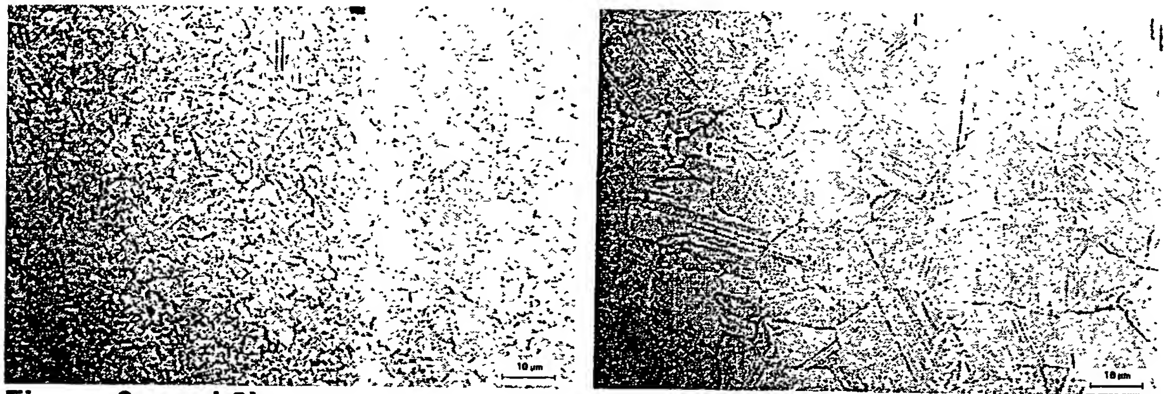


Figure 6a and 6b.

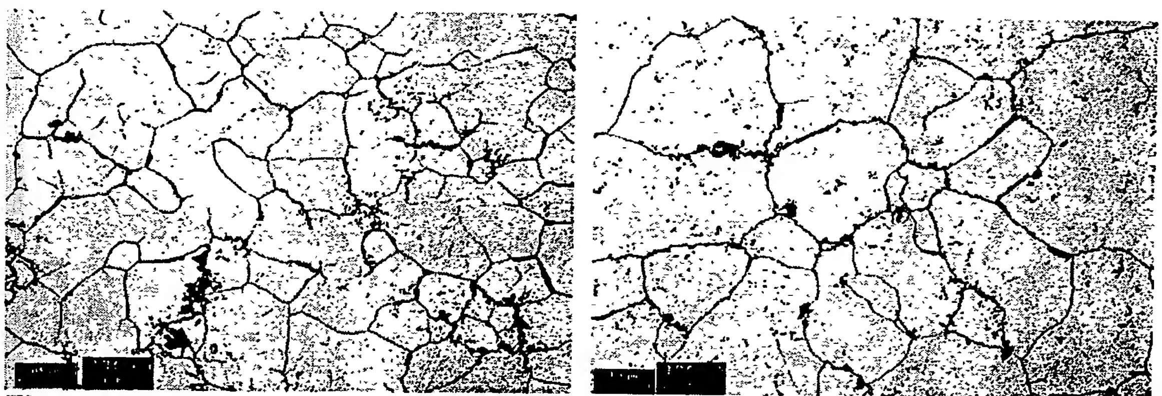


Figure 7a and 7b.

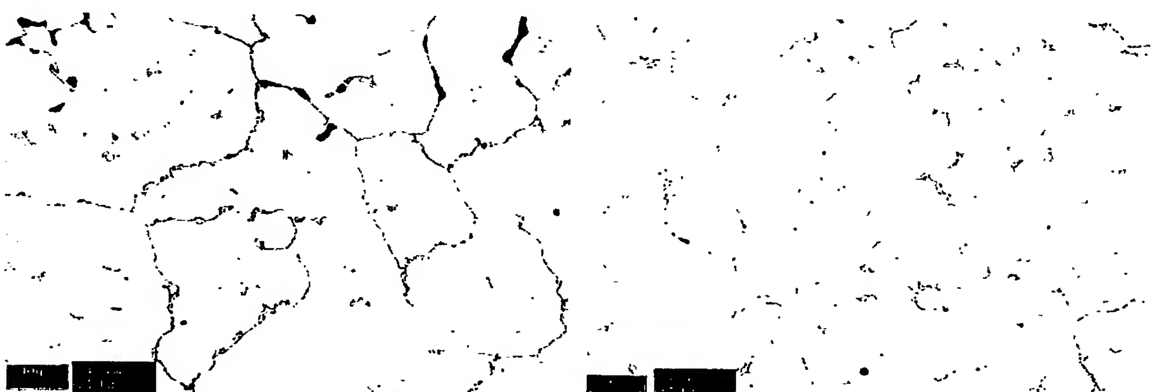


Figure 8a and 8b.

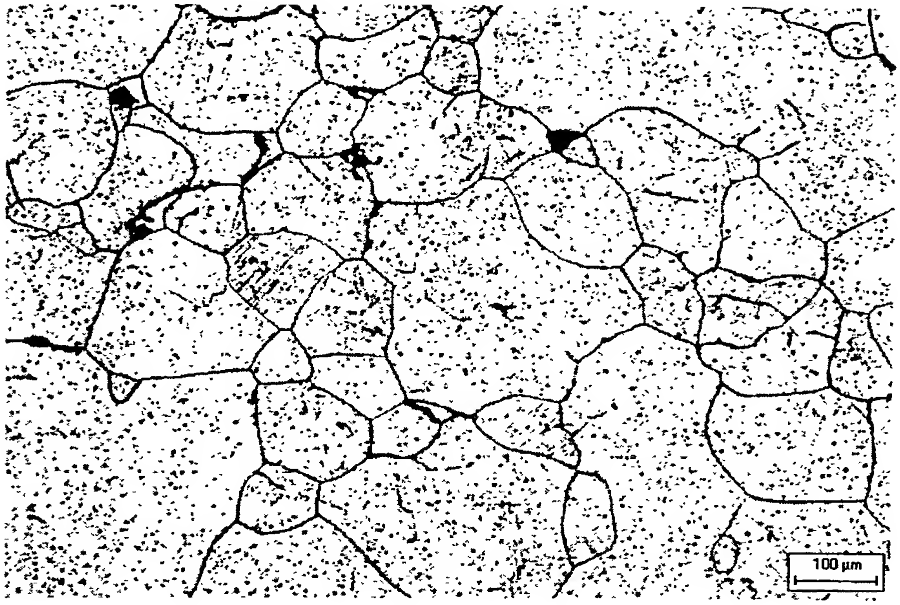


Figure 9.

10049916.073102 #4

Attorney Docket No. S0441/270427
Express Mail Label No. EL209599746US

DECLARATION FOR PATENT APPLICATION

☒ Original ☐ Supplemental ☐ Substitute ☐ PCT

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below), or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Combination of Processes for Making Wrought Components
(Title of the Invention)

the specification of which (check one)

☐ is attached hereto

☒ was filed on 24 August 2000 as PCT/US00/23267

and was amended on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 (a) - (d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified, by checking the box below , any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Applications			Priority Claimed		Copy Attached	
Application Number	Country	Foreign Filing Date (MM/DD/YYYY)	YES	NO	YES	NO

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below and claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application(s) designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

10049916 .073102

Express Mail Label No. EL209599746US
Filed: 19 February 2002
Inventors: Marc Long, et al.
For: **"Combination of Processes for Making Wrought Components"**
Declaration for Patent Application
Page 2

Parent Application Number	Filing Date	Status (Mark Appropriate Column Below)		
		Patented	Pending	Abandoned
60/150,49	08/24/99 (August 24, 1999)			x

As a named inventor, I hereby revoke all prior powers and appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

FIRM NAME: **KILPATRICK STOCKTON LLP,** 1100 Peachtree Street, Suite 2800, Atlanta, Georgia 30309-4530

Attorney and/or Agent	Registration No.
Roger T. Frost	22,176
Charles Y. Lackey	22,707
Anthony B. Askew	24,154
John M. Harrington	25,592
Robert E. Richards	29,105
Donald R. Andersen	28,280
John S. Pratt	29,476
A. Jose Cortina	29,733
James L. Ewing, IV	30,630
Stephen M. Schaetzel	31,418
James Dean Johnson	31,771
Charles W. Calkins	31,814
Larry A. Roberts	31,871
Jamie L. Greene	32,467
George T. Marcou	33,014
Bernard J. Graves, Jr.	33,239
Dean W. Russell	33,452
Richard T. Peterson	35,320
Charles T. Simmons	35,359
Tracy W. Druce	35,493
Eleanor M. Musick	35,623
Nora M. Tocups	35,717
Bruce D. Gray	35,799
Theodore R. Harper	35,890
Geoff L. Sutcliffe	36,348
Stephen B. Parker	36,631
Pat Winston Kennedy	36,970
Leona G. Young	37,266
David P. Lecroy	37,869
Suzanne Seavello Shope	37,933
Mitchell G. Stockwell	39,389
Jeffery B. Arnold	39,540
Suil Kang	39,723

Attorney and/or Agent	Registration No.
Yoncha L. Kundupoglu	41,130
Scott Zimmerman	41,390
Kimberly J. Prior	41,483
Alana G. Kriegsman	41,747
Theodore M. Green	41,801
J. Steven Gardner	41,772
Joni Stutman	42,173
James J. Bindseil	42,326
Heather D. Carmichael	42,389
John K. McDonald	42,860
Sima Singadia Kulkarni	43,732
Camilla Camp Williams	43,992
Christopher J. Chan	44,070
Li K. Wang	44,393
John William Ball, Jr.	44,433
Dawn-Marie Bey	44,442
Tiep H. Nguyen	44,465
John M. Briski	44,562
Michael J. Dimino	44,657
Kristin L. Johnson	44,807
J. Jason Link	44,874
Paul E. Knowlton	44,842
Bambi F. Walters	45,197
Cheryl L. Huseman	45,392
Shelby B. Grier	45,785
Jennifer R. Seng	45,851
Vaibhav P. Kadaba	45,865
Greg Moldafsky	46,514
J. Michael Boggs	46,563
Michael K. Dixon	46,665
Kyle M. Globerman	46,730
Tywanda L. Harris	46,758
Kristin D. Mallatt	46,895

10049916 .073102

Express Mail Label No. EL209599746US
Filed: 19 February 2002
Inventors: Marc Long, et al.
For: **"Combination of Processes for Making Wrought Components"**
Declaration for Patent Application
Page 3

75

Attorney and/or Agent	**Registration No.**
Mary Anthony Merchant	**39,771**
Brenda Ozaki Holmes	**40,339**
Lisa J. Moyles	**40,737**
Michael J. Turton	**40,852**

Attorney and/or Agent	**Registration No.**
Cynthia B. Rothschild	**47,040**
John C. Alemanni	**47,384**
Geoffrey K. Gavin	**47,591**
Janina Malone	**47,768**
Robert M. Stevens	**47,972**

I acknowledge the above-listed attorneys and agents and their firm Kilpatrick Stockton LLP represent my employer (if I am an employee and this application has been or will be assigned to my employer) or the entity with which I have contracted (if I am an independent contractor and this application has been or will be assigned to such entity) and in such cases do not represent me individually. I further acknowledge I have not established, nor will I seek to establish, any personal attorney/client relationship with Kilpatrick Stockton LLP in connection with this application and understand that, should I require legal representation, I will obtain such, at my expense, other than through Kilpatrick Stockton LLP.

Send Correspondence to: John S. Pratt, Esq.
Kilpatrick Stockton LLP
1100 Peachtree Street, Suite 2800
Atlanta, Georgia 30309-4530

Customer No. 23370

23370
PATENT TRADEMARK OFFICE

Direct telephone calls to: James L. Ewing, IV, Esq. (404) 815-6494

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00

Full name of first inventor Marc LONG
Inventor's signature ______ Date Feb. 25, 2002
Residence 911 Meda Street, Memphis, Tennessee 38104
Citizenship France TN
Post Office Address Same as above

2-00

Full name of second inventor Gordon HUNTER
Inventor's signature ______ Date MARCH 12, 2002
Residence 8394 Drury Lane, Germantown, Tennessee 38139
Citizenship U.S. TN
Post Office Address Same as above

1305074